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(56) Documents Cited
EP 0333286 A2 WO 92/03323 A1 US 4788974 A
US 3488844 A

(58) Field of Search
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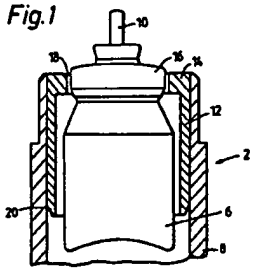
(54) Inhaler

(57) A component (2) of an inhaler adapted to be assembled with one or more other components (4) to complete the inhaler, comprises a reservoir of medicament (6) having a dispensing port (10), a housing (8) substantially enveloping the reservoir and retaining means (12) which prevents removal of the reservoir (6) from the housing (8), maintains the dispensing port (10) aligned in a predetermined direction and allows movement of the reservoir (6) within the housing (8).



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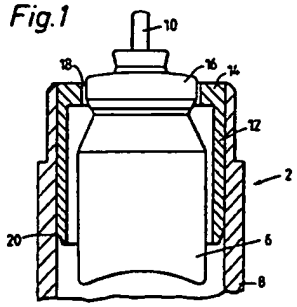

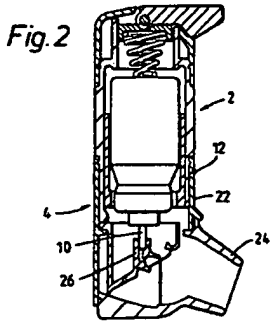

INHALER

This invention relates to inhalers and in particular to pressurised inhalers.

Since the metered dose pressurised inhaler was introduced in the mid-1950's, inhalation has become the most widely used route for delivering bronchodilators, offering a rapid onset of action and a low instance of systemic side effects. More recently, inhalation from a pressurised inhaler has been a route selected for the administration of other drugs, e.g., ergotamine, which are not primarily concerned with the treatment of a bronchial malady.

The metered dose inhaler is dependent upon the propulsive force of a propellant system used in its manufacture. The propellant generally comprises a mixture of liquified chlorofluorocarbons (CFC's) which are selected to provide the desired vapour pressure and stability of the formulation. Propellants 11, 12 and 114 are the most widely used propellants in aerosol formulations for inhalation administration. Recently, non-CFC propellant systems have been proposed in view of the adverse effect of CFC's on the ozone layer. The drugs are formulated in the propellant system as a solution or dispersion, generally in the presence of a surfactant.

The drug/propellant formulation is contained in an aerosol vial equipped with a metered dose valve. The aerosol vial is inserted within an adaptor which comprises a housing having a mouthpiece or nasal port through which the patient inhales the drug during actuation of the valve. The adaptor may be of the "press and breathe" type which requires the patient to actuate the valve during inhalation or of the "inhalation-actuated" type which actuates the valve as the patient inhales.

Inhalation activatable dispensers for use with aerosol containers are described in British Patent Specification Nos. 1269554, 1335378, 1392192 and 2061116 and United States Patent Nos. 3,456,644, 3,456,645, 3,456,646, 3,565,070, 3,598,294, 3,814,297, 3,605,738, 3,732,864, 3,636,949, 3,789,843 and 3,187,748 and German Patent No. 3040641.

European Patent No. 147028 discloses an inhalation activatable dispenser for use with an aerosol container in which a latch mechanism releasing vane is pivotally mounted in an air passage between an aerosol outlet valve and a mouthpiece, which latch mechanism cannot be released if force to activate the dispenser is not applied before a patient inhales.

This inhalation device, commercially available from Minnesota Mining and Mining Manufacturing Company under the registered trade mark AUTOHALER, has been received favourably by patients and doctors since it not only overcomes the hand-lung co-ordination problem but it does so at a very low triggering flow-rate (approximately 30 litres/minute) essentially silently, and with a very compact design barely larger than a standard inhaler.

Some of the inhalation activatable inhalers are formed of two main parts, one part which holds the aerosol container and the second part comprising the mouthpiece and nozzle block into which the valve stem of the aerosol container is inserted. It is important that the stem is correctly aligned with the nozzle block when the two parts are assembled otherwise damage and/or failure of the unit may occur. Such assembly may take place not only during manufacture of the inhaler but also during the lifetime of the product since it may be necessary to disassemble the parts for washing.

One problem associated with the use of aerosol containers is that relative movement between the valve stem and aerosol container is required to dispense a dose and in many devices it is not possible to secure the

aerosol container to one part of the device since this would prevent the required movement. Thus, it is desirable to be able to retain an aerosol container in a part of an inhaler which will ensure the correct alignment of the aerosol container and yet retain the ability for the aerosol container to move sufficiently to operate the valve.

According to the present invention there is provided a component of an inhaler adapted to be assembled with one or more other components to complete the inhaler, the component comprising a reservoir of medicament having a dispensing port, a housing substantially enveloping the reservoir and retaining means which prevents removal of the reservoir from the housing, maintains the dispensing port aligned in a predetermined direction and allows movement of the reservoir within the housing.

The invention is particularly useful with aerosol containers which may be accommodated within a cylindrical housing and maintained in place by an annular retaining means positioned within the mouth of the cylinder with the valve stem protruding thereby preventing removal of the aerosol container and holding the container with the valve stem correctly aligned. The annular retaining means may be adhered in place, may be a force fit within the housing or have mechanical engaging means. Preferably the retaining means comprises a skirt portion extending along the inner cylindrical wall of the housing.

The component of the invention has the following advantages:

i) Guaranteed correct assembly of the device.

ii) Prevents the substitution of alternative aerosol cans which would not necessarily function properly in the device.

iii) Allows pre-packaged top assemblies and cans to be marketed.

iv) During cleaning the patient has one less part to handle, simplifying reassembly.

The invention will now be described with reference to the accompanying drawings in which:

Figure 1 represents a section through part of an inhaler showing the retaining means, and

Figure 2 represents a section through an inhaler showing the part of Figure 1.

Figure 1 shows a portion of a component (2) which is assembled with component (4) (Figure 2) to form an inhaler. The inhaler illustrated is inhalation activatable and is of the type disclosed in EP-147028.

An aerosol container (6) is accommodated within the housing (8) of component (2) with the valve stem (10) projecting outwardly from the housing. In order to maintain the alignment of the valve stem (10) in the longitudinal direction, a retaining means (12) is positioned within the housing (8). The retaining means (12) comprises an annular ring (14) which is dimensioned to allow a clearance fit of the valve ferrule (16) but prevent removal of the aerosol container (6) since the aperture (18) has a smaller diameter than the outer diameter of the aerosol container (6). The retaining means (12) is held in place within the housing by a skirt portion (20) which extends along the inner wall of the housing (8). The skirt portion may be a force fit within the housing (8), may be adhered to the inner wall or may have mechanical engaging means, e.g. complimentary projections and recesses (not shown). The retaining means allows limited movement of the aerosol container (6) in the longitudinal direction whilst maintaining the alignment of the valve stem (10).

Referring to Figure 2, the components (2, 4) are combined to form the inhaler. The component (4) comprises a housing (22), a mouthpiece (24) and a nozzle block (26). The component (4) also comprises a breath-

actuated mechanism which has been omitted in the interests of clarity.

The components (2, 4) are provided with complimentary threads which allows the two components to be assembled by rotation. During assembly it is essential that the valve stem (10) is located within the nozzle block (26). Failure to ensure correct alignment could result in the valve stem (10) completely missing the nozzle block, rendering the inhaler inoperable, or could lead to the valve stem or nozzle block being damaged by forces generated during assembly of the two components (2, 4). The retaining means (12) ensures the valve stem (10) is correctly aligned and will be introduced into the nozzle block (26) as the two components (2, 4) are assembled.

CLAIMS

1. A component of an inhaler adapted to be assembled with one or more other components to complete the inhaler, the component comprising a reservoir of medicament having a dispensing port, a housing substantially enveloping the reservoir and retaining means which prevents removal of the reservoir from the housing, maintains the dispensing port aligned in a predetermined direction and allows movement of the reservoir within the housing.

2. A component of an inhaler as claimed in Claim 1 in which the reservoir is an aerosol container.

3. A component of an inhaler as claimed in Claim 1 or Claim 2 in which the housing is substantially cylindrical.

4. A component of an inhaler as claimed in Claim 3 in which the retaining means is annular and fits within the cylindrical housing, the dispensing port projecting through the annular.

5. A component of an inhaler as claimed in Claim 4 in which the retaining means comprises a skirt extending along the inner wall of the housing.

atents Act 1977
Examiner's report to the Comptroller under Section 17 (The Search Report)

Application number
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Relevant Technical fields
(i) UK Cl (Edition L) A5T (TBE, TCR, TDC, TEB)
(ii) Int Cl (Edition 5) A61H

Search Examiner
H SIDDIQUE

Databases (see over)
(i) UK Patent Office
(ii)

Date of Search
27 JULY 1993

Documents considered relevant following a search in respect of claims 1-5

Category (see over)	Identity of document and relevant passages		Relevant to claim(s)
X	EP 0186280 A2	(LANDIS) housing 10, reservoir 24 moved by spring, retaining means 44 etc	1, 3
X	WO 92/09323 A1	(HORTON) housing 5, reservoir 20/25 moved by spring 80, retainer defined by wall cross 10	1-4
A	US 4796614		1
X	US 3456644	(THIEL) Figure 10, 11; retaining means 83, 84	1-3

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Category	Identity of document and relevant passages	Relevant to claim

Categories of documents

X: Document indicating lack of novelty or of inventive step.

Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.

A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family, corresponding document.

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).